DETAILED ACTION

Respond to Amendments and Arguments

1. The response filed on **6/29/11** has been entered.

Applicant's arguments filed 6/29/11 have been fully considered but they are not deemed to be persuasive.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1, 4-5, 7-21 and 23-24 are pending in this office action.

4. The rejection of claims 1, 7, 10-11 and 21 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn due to the amendment of the claims.

5. The rejection of claims 1, 4-5, 7-21 and 23-24 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of (U.S. Patent No. 6,984,665) in view of Guidance for Industry (2002) is withdrawn due to duplicate rejection made.

Maintained Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

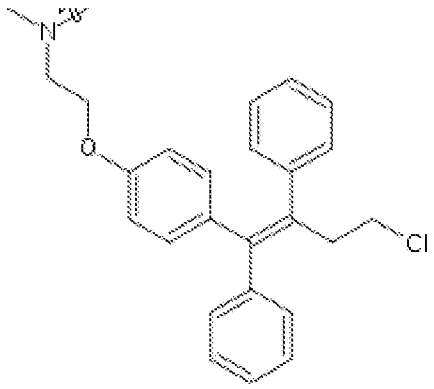
Claims 1, 4-5, 7, 10-11, 14 and 18-20 stand rejected under 35 U.S.C. 103(a) as being unpatentable over DeGregorio et al. (US 5,750,576) in view of Anttila (1997) and further in view of Guidance for Industry (2002, already of record).

DeGregorio et al. teaches treating osteoporosis by administering ospemifene (see abstract), as required by instant claims 1, 7, 10-11, 14 in a pharmaceutically acceptable salt is obvious since it is in a pharmaceutical composition. DeGregorio et al. further teaches that ospemifene can be orally administered in the varying dosage amounts of 5-100 mg/day (which overlaps the recited ranges of 30-90 mg/day of ospemifene; as it relates to claims 10-11 and 19-20) for the treatment of osteoporosis as (i.e., as it relates to claims 7 and 18, see abstract, col. 3, lines 1-10 and 59-64)).

However, DeGregorio et al. does not teach the administration of the drug in connection with intake of foodstuff being taken shortly before, during or shortly after administration (as required by instant claim 1 for example). DeGregorio et al. is also silent of the specific dosages recited by instant claims 11 for example. Nonetheless teaches overlapping ranges that will motivate one of ordinary skill in the art to administer different dosages and determine the best effective dose.

Anttila is added to show that structurally similar compounds are known in the art to be administered with or without food.

Anttila teaches administering 60 mg/day of a structurally similar compound



toremifene Toremifene administered orally during or after meal (food) and therefore reasonably meets the limitation of claims 1. The recitation that foodstuff having nutritional value is obvious because all food have nutritional value and therefore would cause secretion of bile acids, and enhance bioavailability of toremifene. Anttila teaches the drug is taken following a meal thus shortly after meal and after fasting which reasonable encompasses “during, after or at a certain time interval to meals” (see introduction as required by instant claims 1, see abstract).

Guidance for Industry teaches food effect bioavailability are conducted with new drugs shortly after a meal and compared to fasting condition (see Sec I and II, page 1) wherein Guidance for Industry teaches that food effects are generally greatest when the drug product is administered shortly after a meal is ingested (see page 2, lines 10-16 from the top).

It would have been obvious to one of ordinary skill in the art to expand the teaching of DeGregorio et al to include the teachings of Anttila and administer the drug of DeGregorio at a dosage of 60 mg/day for the treatment of osteoporosis with a reasonable expectation of success because DeGregorio teaches a dosage range that encompasses the recited range.

Because Anttila teaches a structurally similar compound can be administered with or without food and DeGregorio is silent of food intake with the drug ospemifene, one of ordinary skill in the art would have been motivated to administer DeGregorio's drug with or without food with the expectation of success that the effect will be the same when ospemifene is administered with or without food.

One of ordinary skill in the art would have been motivated to expand Degregorio method of treating osteoporosis with ospemifene to include Anttila dosage amount and teaching of a structurally similar compound administered with or without food to include the teachings of Guidance for Industry for food effect of bioavailability for orally administered drugs with a reasonable expectation of success because Guidance for Industry teaches that drugs should be conducted under fed and fasting conditions wherein under fed conditions the drug can be administered 30 mines after meal (see

section E, page 6) and entire teaching). Therefore the administration of ospemifene within one hour, no later than 0.5 hour with food intake is within the purview of the skilled artisan. Thus the teaching of Anttila "that findings may help precision of administration instructions (e.g. administration during or after meals, or at a certain time interval to meals) are well known in the art and are routinely practiced" as taught by Guidance for Industry, the varying point of administering the drug ospemifene (such as 2 hours, one hour, 0.5 hour) after starting the food intake is obvious to be optimized in order to find the most effective time interval for administration, as taught by Anttila (see introduction).

Thus the combination of the cited prior art would have been prima facie obvious at the time the claimed invention was filed.

Applicant argues that the Examiner admits that DeGregorio does not teach the administration of the drug in connection with the intake of food, much less within a certain time period of eating and erroneously argues that all food has nutritional value, and that The Examiner also admits that Anttila teaches the administration of a different drug (toremifene) with food. The Examiner continues to erroneously argue that administering toremifene with food inherently enhances the bioavailability of toremifene. Additionally Applicant argues that it is improper in this context to simply hold that the measure of success is that administering ospemifene with food would not impair the bioavailability. Finally Applicant argues that Because DeGregorio et al. in view of Anttila and further in view of Guidance for Industry (2002) do not teach or suggest a method to enhance the bioavailability of orally-administered ospemifene, much a less a significant

2-3 fold improvement as demonstrated by Applicant, they do not render obvious the claimed invention.

In response contrary to Applicant's assertion that DeGregorio fails to teach administration of the drug with food and Anttila teaches the administration of a different drug with food is found not persuasive because DeGregorio et al. teaches ospemifene (see abstract), as required by instant claims 1-2, 7, 10-11, 14 in a pharmaceutically acceptable salt is obvious since it is in a pharmaceutical composition. DeGregorio et al. further teaches administering orally 5-100 mg/day of ospemifene (as it relates to claims 10-11 and 19-20) for the treatment of osteoporosis as (i.e., as it relates to claims 7 and 18, see abstract, col. 3, lines 1-10 and 59-64)). Because Anttila teaches a structurally similar compound can be administered with or without food and DeGregorio is silent of food intake with the drug ospemifene, one of ordinary skill in the art would have been motivated to administer DeGregorio's drug with or without food with the expectation of success that the effect will be the same when ospemifene is administered with or without food. Therefore such structurally homologous compounds are expected to possess similar properties. It has been held that compounds that are structurally homologous to prior art compounds are prima facie obvious. Guidance for industry specifically teaches that drugs should be tested under both fed and fasting conditions to determine how to administer the drug. Therefore the administration of ospemifene within one hour, no later than 0.5 hour with food intake is within the purview of the skilled artisan. Thus the teaching of Anttila "that findings may help precision of administration instructions (e.g. administration during or after meals, or at a certain time interval to

meals) are well known in the art and are routinely practiced" as taught by Guidance for Industry, the varying point of administering the drug ospemifene (such as 1 hour before starting the food intake and 2 hours after starting the food intake) is obvious to be optimized in order to find the most effective time interval for administration, as taught by Anttila (see introduction). It is reasonable that ospemifene is administered within 2 hours after starting the food intake. There is nothing unexpected in administration of a drug with food.

Applicant's argument is found not persuasive for the reasons already made of record.

With regards to the unexpected result Applicant argues that The Declaration also establishes that even though ospemifene and toremifene are structural relatives, their pharmacokinetics are significantly different in regard to their elimination rates and metabolism (Lammintausta Declaration ¶22). The Declaration also confirms that applicant unexpectedly found a significant 2-3 fold improvement of ospemifene bioavailability when administered with food. This unexpected finding of significant 2-3 fold improvement of ospemifene bioavailability with food has very significant practical consequences. For example, in a large clinical study, ospemifene administered in 60 mg daily doses given with food shows significant benefit in treating dyspareunia

In response Applicant's asserts that there is 2-3 fold improvement in bioavailability when ospemifene is administered with food 1 hour before starting food intake and 2 hours after food intake, however there is no showing in comparison how toremifene acts under the same condition (i.e., 1hour before food intake and 2 hours

after food intake). All Applicant has done is asserts that food enhances the bioavailability of ospemifene within time frame 1 hour before food intake and 2 hours after food intake. The reliance that food has no effect on Anttila ‘s drug toremifene is found not persuasive because a side by side comparison wherein Anttila’s drug toremifene is administered the same way as that claimed and the results compared. Therefore the unexpected result would be expected based on the combined teachings of the prior art for the following reasons. i) DeGregorio's specifically teach administering 5-100 mg/day, thus one of ordinary skill in the art would reasonable administer 60 mg of ospemifene (thus substituting the dosage of DeGregorio with Anttila) which would also result in the significant benefit in treating dyspareunia also. ii) Guidance for industry specifically teach that food changes the bioavailability of drug additionally Guidance for Industry also teaches that other factors affect bioavailability of drugs such as excipients (see page 2 under Food Effects on Drug Products). It is reasonable that the drugs (i.e., ospemifene and toremifene) under the same conditions would react the same. Additionally Guidance specifically teaches that drugs should be tested under both fed and fasting conditions to determine how to administer the drug. Therefore the administration of ospemifene by 1 hour before starting the food intake and 2 hours after starting the food intake is within the purview of the skilled artisan, it is reasonable that ospemifene is administered within 2 hours after starting the food intake. Additionally, there is no difference in the drug that would enhance bioavailability when orally administered. Applicant's drug is the same as that of DeGregorio, there is no chemical

difference in the formulation of the drug. If the same drug is administered orally it will therefore have the same bioavailability.

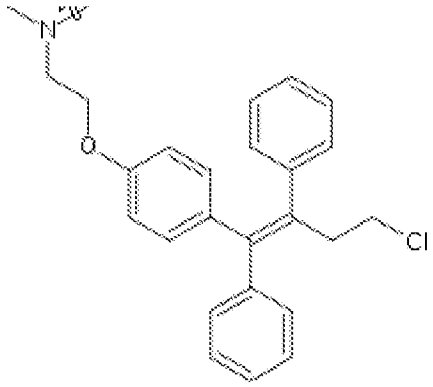
7. Claims 1, 8-9, 12-13, 15-17 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Halonen et al. (US 6,245,819) in view of Anttila (1997) and Guidance for Industry (2002).

8. Halonen teaches administering ospemifene (FC-1271) an estrogen receptor modulator to women suffering from vaginal symptoms (as required by instant claim 9 wherein the drug is administered at a dosage from 30, 60 and 90 (as required by instant claims 12-13, 16-17 and 23-24, see col. 2, lines 60-65). With regards to instant claim 8, Halonen teaches treating vaginal dryness (i.e., mucosal atrophy, see col. 2, lines 29-35).

However Halonen fails to teach treating specifically inhibiting urogenital atrophy as required by instant claim 21 and also fails to teach administration of the drug with a connection of with intake of foodstuff being taken shortly before, during or shortly after administration.

Anttila is added to show that structurally similar compounds are known in the art to be administered with or without food.

Anttila teaches administering 60 mg/day of a structurally similar compound



toremifene Toremifene administered orally during or after meal (food) and therefore reasonably meets the limitation of claims 1. The recitation that foodstuff having nutritional value is obvious because all food have nutritional value and therefore would cause secretion of bile acids, and enhance bioavailability of toremifene. Anttila teaches the food is taken following a meal thus shortly after meal and after fasting which reasonable encompasses “during, after or at a certain time interval to meals” (see introduction as required by instant claims 1, see abstract).

Guidance for Industry teaches food effect bioavailability are conducted with new drugs shortly after a meal and compared to fasting condition (see Sec I and II, page 1) wherein Guidance for Industry teaches that food effects are generally greatest when the drug product is administered shortly after a meal is ingested (see page 2, lines 10-16 from the top).

Even though Halonen did not specifically teach treating urogenital atrophy, in the background section Halonen teaches that during and after menopause elderly women develop symptoms which are due to estrogen deficiency such as vaginal dryness (i.e., mucosal atrophy), urinary incontinence (i.e., urogenital atrophy).

Therefore based on the teaching alone one of ordinary skill in the art would have been motivated to inhibit vaginal atrophy and urogenital atrophy with ospemifene because these disease are estrogen related disorders and reasonable to be treated with an estrogen receptor modulator.

It would have been obvious to one of ordinary skill in the art at the time of filing the instant application to expand the teachings of Halonen to include Anttila's and Guidance for Industry for the treatment of vaginal and urogenital atrophies because Halonen teaches that ospemifene is used for the treatment of such diseases as explained supra.

Based on the teaching of Anttila "that findings may help precision of administration instructions (e.g. administration during or after meals, or at a certain time interval to meals) are well known in the art and are routinely practiced" as taught by Guidance for Industry, the varying point of administering the drug ospemifene (such as 2 hours, one hour, 0.5 hour) after starting the food intake is obvious to be optimized in order to find the most effective time interval for administration, as taught by Anttila (see introduction).

Applicant argues that neither Halonen et al. nor Anttila and Guidance for industry teach the bioavailability of orally administering ospemifene would enhance food intake.

In response, Applicant has totally ignored the rationale behind the rejection under 35 USC 103. Halonen et al teach treating women suffering from vaginal symptoms (such as dryness) by orally administering the claimed drug ospemifene. Bioavailability is a preamble that does not affect the treatment of skin atrophy.

9. As to the assertion that the Examiner has ignored the unexpected result is found not persuasive because the declaration was addressed and reasons why it was found not persuasive stated. Additionally the argument that it is the bile acid secreted after food and not the food is the critical factor in increasing the absorption on ospemifene. This is found not persuasive because whether the drug is administered with food or no food the acids from the bile will induce absorption of the drug regardless. It is reasonable that ospemifene is administered within 2 hours after starting the food intake for example after breakfast. Additionally, there is no difference in the drug that would enhance bioavailability when orally administered. Applicant's drug is the same as that of Halonen, there is no chemical difference in the formulation of the drug. If the same drug is administered orally it will therefore have the same bioavailability. Whether enhanced bioavailability is claimed or not does not change the property of the drug when administered. See supra with regards to the arguments under unexpected result.

Maintained Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 4-5, 7-21 and 23-24 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of (U.S. Patent No. 6,984,665) in view of Guidance for Industry (2002) for the reasons already made of record.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant claims and the patented claims recite treating or inhibiting urinary symptoms. Even though the patent is silent to teaching the effect of food on the drug, Guidance for Industry teaches food effect bioavailability are conducted with new drugs shortly after a meal and compared to fasting condition (see Sec I and II, page 1) wherein Guidance for Industry teaches that food effects are generally greatest when the drug product is administered shortly after a meal is ingested (see page 2, lines 10-16 from the top).

Therefore one of ordinary skill in the art would be motivated to administer food with the drug based on the teaching of Guidance for Industry.

It should be noted that the claims of the patent '665 are drawn to a method for the treatment of urinary symptoms related to urogenital atrophy in women, or to administering effective amounts of formula (I), (i.e., ospemifene).

The "665 patent differs from the claimed invention insofar as it fails to expressly claim a method of enhancing bioavailability. The '665 patent only sets forth a method of treatment or prevention of urinary symptoms related to urogenital atrophy as noted above.

Guidance for Industry teaches food effect bioavailability are conducted with new drugs shortly after a meal and compared to fasting condition (see Sec I and II, page 1) wherein Guidance for Industry teaches that food effects are generally greatest when the drug product is administered shortly after a meal is ingested (see page 2, lines 10-16 from the top).

However, it is contended that a method for treatment skin of atrophy, or epithelial or mucosal atrophy using compound the formula (I), would intrinsically treat urogenital atrophy, as evidenced by the specification of the '665 patent. For example, the '665 patent defines the symptoms related to urogenital atrophy as urinary and vaginal symptoms (see page3, lines 57-60). Thus, treating a woman with symptoms related to a urogenital atrophy would treat a woman with urinary symptoms when ospemifene is administered with or without food as taught by Guidance for Industry.

Applicant argues that the combination of reference is deficient in teaching or suggesting enhancing bioavailability.

In response Applicant's argument is found not persuasive because in the morning it is reasonable that ospemifene is administered within 2 hours after starting the food intake and treatment would occur regardless of bioavailability. Whether enhanced bioavailability is claimed or not does not change the property of the drug when administered.

11. Claims 1, 4-5, 7-21 and 23-24 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of US 6,245,819 in view of Guidance for Industry for the reasons already made of record.

The instant claims (8 and 15) are drawn to a method of treatment of symptoms related to skin atrophy, or to treating epithelial or mucosal atrophy in women, comprising administering to the woman an effective amount of formula (I) which ospemifene… .

The "819 patent differs from the claimed invention insofar as it fails to expressly claim a method of enhancing bioavailability. The '819 patent only sets forth a method of treatment or prevention of urinary symptoms related to urogenital atrophy as noted above.

However, it is contended that a method for treatment skin of atrophy, or epithelial or mucosal atrophy using compound the formula (I), would inherently treat urogenital atrophy, as evidenced by the specification of the '665 patent. For example,

the '665 patent defines the symptoms related to urogenital atrophy as urinary and vaginal symptoms (see page3, lines 57-60). Thus, treating a woman with symptoms related to a urogenital atrophy would inherently treat a woman with urinary symptoms when ospemifene is administered with or without food. Whether enhanced bioavailability is claimed or not does not change the property of the drug when administered.

Applicant argues that the combination of reference is deficient in teaching or suggesting enhancing bioavailability.

In response Applicant's argument is found not persuasive because in the morning it is reasonable that ospemifene is administered within 2 hours after starting the food intake.

Affidavit

12. The affidavit submitted by Risto Lammintausta under 37 CFR 1.132 filed 4/30/10 is insufficient to overcome the rejection of claims 1, 3-5 and 7-24 based upon the rejection under 35 USC 103 as set forth in the this action because:

Appellant argues that “Ospemifene is a selective estrogen receptor modulator or a "SERM." A SERM, by definition, displays estrogenicity in at least some tissues (i.e., agonism), but may have no estrogen effect in other tissues, and may in fact block estrogen action in some tissues (i.e. antagonism). (Burger HG: Selective

Estrogen Receptor Modulators. Horm.Res.2000;53 Suppl 3:25-29)" and also states that "Current evidence suggests that the pharmacology of SERMs with respect to their estrogen-mediated effects is potentially unique to each member of the class".

Appellant further argues that "Contrary to the Examiner's assertions, Anttila does not disclose administering a metabolite of toremifene. Anttila discloses administering 60 mg tablets of toremifene. Anttila does measure the blood levels of a major metabolite of toremifene, namely N-demethyltoremifene (or desmethyltoremifene), but no metabolite was administered".

That "[t]he Examiner is also incorrect in his assertion that food would inherently enhance the bioavailability of toremifene. The Anttila reference teaches that toremifene "works equally well with or without administration of food" and "The DeGregorio et al. reference relates to the use of ospemifene to treat or prevent osteoporosis. The DeGregorio et al, reference does not teach the administration of a drug with a meal nor does it teach the use of ospemifene to treat either vaginal atrophy or symptoms thereof"

Additionally Applicant argues that the unexpected and significant increase in bioavailability.

In response to Applicant's argument that ospemifene is a selective estrogen receptor modulator or a "SERM." A SERM, by definition, displays estrogenicity in at least some tissues (i.e., agonism), but may have no estrogen effect in other tissues is not the issue here, the claims do not require that the drug ospemifene displays estrogenicity. The claims recite a method of enhancing the bioavailability which does not affect its selectivity to specific organs. When the drug is enhanced it will still maintain its

specificity. Applicant's asserts that there is 2-3 fold improvement in bioavailability when ospemifene is administered with food 1 hour before starting food intake and 2 hours after food intake, however there is no showing in comparison how toremifene acts under the same condition (i.e., 1hour before food intake and 2 hours after food intake). All Applicant has done is asserts that food enhances the bioavailability of ospemifene within time frame 1 hour before food intake and 2 hours after food intake. The reliance that food has no effect on Anttila 's drug toremifene is found not persuasive because a side by side comparison wherein Anttila's drug toremifene is administered the same way as that claimed and the results compared has not been done.

Based on Guidance for Industry which teaches food effect bioavailability are conducted with new drugs shortly after a meal and compared to fasting condition (see Sec I and II, page 1) it has clearly showed that every drug undergoes how food affects administration and then prescribed accordingly.

Also a lot of factors can affect bioavailability of orally administered drugs such as gastric emptying, intestinal transit time, hepatic first pass metabolism, gastrointestinal and hepatic blood flow diet and dosage forms absent factual evidence to the contrary.

In summary

As discussed above DeGregorio et al. teaches ospemifene (see abstract), as required by instant claims 1-2, 7, 10-11, 14 in a pharmaceutically acceptable salt is obvious since it is in a pharmaceutical composition. DeGregorio et al. further teaches administering orally 5-100 mg/day of ospemifene (as it relates to claims 10-11 and 19-

20) for the treatment of osteoporosis as (i.e., as it relates to claims 7 and 18, see abstract, col. 3, lines 1-10 and 59-64)).

Anttila teaches administering toremifene at a dose of 60 mg a day (structurally similar to ospemifene) with food or without food. Guidance for Industry teaches food effect bioavailability are conducted with new drugs shortly after a meal and compared to fasting condition (see Sec I and II, page 1) wherein Guidance for Industry teaches that food effects are generally greatest when the drug product is administered shortly after a meal is ingested (see page 2, lines 10-16 from the top).

13. No claim is allowed.

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHIRLEY V. GEMBEH whose telephone number is (571)272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, BRANDON FETTEROLF can be reached on 571-272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SHIRLEY V GEMBEH/
Examiner, Art Unit 1628
8.7/11

/Brandon J Fetterolf/
Supervisory Patent Examiner, Art Unit 1628